

Remarks

Claims 18-33 were pending in the subject application. By this Amendment, claims 18, 25 and 27- 29 have been amended, claims 24 and 26 have been cancelled and new claims 34 and 35 have been added. No new matter has been added by these amendments. Accordingly, claims 18-23, 25, and 27-35 are pending in the subject application and before the Examiner for consideration.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 18-33 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The applicants respectfully traverse this ground for rejection to the extent that it might be applied to the claims now presented for examination.

Please note that the claims have been amended herein such that the issues set forth in Paragraphs 1 to 4 and 6 of this rejection have been rendered moot.

With regard to Paragraph 5, claim 24 has now been cancelled herein.

With regard to Paragraph 7, claim 26 has been cancelled herein.

With regard to Paragraphs 8 and 9, the word "related" has been deleted from these claims.

In view of the claim amendments and cancellations as set forth herein, the applicants respectfully submit that the claims now presented for examination clearly and unambiguously set forth the metes and bounds of the claimed invention. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Claims 29-33 have been rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The applicants respectfully traverse this ground for rejection because the skilled artisan could readily, and without undue experimentation, practice the full scope of this invention as presently claimed.

Although the applicants believe that the claims as originally presented were fully enabled, in order to expedite prosecution, the method of use claims have been amended herein such that they are now directed only to the separation, isolation, and/or purification of peptides and proteins.

Please note that these claims are not intended to be “reach through” claims. An example of a “reach through” claim perhaps might be if the applicants tried to claim compounds that were discovered using the ligands of the subject invention. Here, the applicants are merely claiming a straightforward use of their claimed compounds.

The invention lies, at least in part, in the use of triazine rings to provide any suitable combination of affinity ligands. Similarly, the nature of each of M and each Y is not critical to the definition of the invention, since the product can be used in any reaction for which affinity ligands are suitable. Such ligands are widely used for separation, isolation, and purification.

It should be noted that the requirement for some experimentation and/or screening does not necessarily make a claim non-enabled. “Enablement is not precluded by the necessity for some experimentation such as routine screening. . . . A considerable amount of experimentation is permissible, if it is merely routine . . .” (emphasis added). *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988). In the current case, any experimentation needed would be routine given the guidance provided in the subject application.

It is important to bear in mind that for an invention to be enabled under the first paragraph of §112, the specification need only teach a person of ordinary skill in the art “how to make” and “how to use” the invention. It is further noted that the sheer number of compounds which may fall within the scope of a claim is not determinative of the enablement of the specification. See, e.g., *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976), where the court observed that a large but finite list of materials, in combination with a teaching of how to carry out the invention, was enabling for purposes of §112. The applicants are cognizant of the duty under §112, first paragraph, to provide sufficient teaching in the specification to enable one skilled in the art to practice the invention as claimed without undue experimentation.

A person of ordinary skill in this art could readily and without undo experimentation practice the methods as now claimed by the current applicants. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Claims 18-22 and 24-33 have been rejected under 35 U.S.C. §102(b) as being anticipated by Lowik *et al.* (WO 01/42228). The applicants respectfully traverse this ground for rejection because the Lowik *et al.* reference does not disclose each and every element of the claimed invention.

It is a basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

Please note that the Lowik *et al.* reference does not disclose compounds meeting the definition of “X” in the claims as amended here. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on Lowik *et al.*

Claims 18-20 and 24-33 have been rejected under 35 U.S.C. §102(b) as being anticipated by Atkinson *et al.* (GB 2 053 926). The applicants respectfully traverse this ground for rejection because the Atkinson *et al.* reference does not disclose each and every element of the claimed invention.

Please note that the Atkinson *et al.* reference does not disclose compounds meeting the definition of “X” in the claims as amended here. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on Atkinson *et al.*

Claims 18-20 and 24-28 have been rejected under 35 U.S.C. §102(b) as being anticipated by Dore *et al.* (GB 2 149 808). The applicants respectfully traverse this ground for rejection because the Dore *et al.* reference does not disclose each and every element of the claimed invention.

Please note that the Dore *et al.* reference does not disclose compounds meeting the definition of “X” in the claims as amended here. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on Dore *et al.*

Claims 18-20 and 24-28 have been rejected under 35 U.S.C. §102(b) as being anticipated by Adam *et al.* (EP 0 122 458). The applicants respectfully traverse this ground for rejection because the Adam *et al.* reference does not disclose each and every element of the claimed invention.

Please note that the Adam *et al.* reference does not disclose compounds meeting the definition of “X” in the claims as amended here. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on Adam *et al.*

Claims 18-22 and 24-28 have been rejected under 35 U.S.C. §102(b) as being anticipated by Cipolli *et al.* (EP 0 542 374). The applicants respectfully traverse this ground for rejection because the Cipolli *et al.* reference does not disclose each and every element of the claimed invention.

Please note that the Cipolli *et al.* reference does not disclose compounds meeting the definition of “M and Y” in the claims as amended here. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on Cipolli *et al.*

Claims 18-22 and 24-28 have been rejected under 35 U.S.C. §102(b) as being anticipated by Lawery *et al.* (U.S. Patent No. 6,482,255). The applicants respectfully traverse this ground for rejection because the Lawery *et al.* reference does not disclose each and every element of the claimed invention.

Please note that the Lawery *et al.* reference does not disclose compounds meeting the definition of “X” in the claims as amended here. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on Lawery *et al.*

Claims 18-22 and 24-28 have been rejected under 35 U.S.C. §102(b) as being anticipated by Karrer *et al.* (U.S. Patent No. 4,731,393). The applicants respectfully traverse this ground for rejection because the Karrer *et al.* reference does not disclose each and every element of the claimed invention.

Please note that the Karrer *et al.* reference does not disclose compounds meeting the definition of “M” and “Y” in the claims as amended here. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on Karrer *et al.*

Claims 1-22 and 24-33 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Dore *et al.*, Adam *et al.*, Cipolli *et al.*, Lawrey *et al.* or Karrer *et al.* in view of Lowik *et al.* (WO 01/42228) and Atkinson *et al.* (GB 2 053,926). The applicants respectfully traverse this ground for rejection because the cited references, taken either alone or in combination, do not disclose or suggest the claimed subject matter.

The present invention addresses the problem of providing ligand libraries comprising 2 or more triazine groups with attached functional groups (Y), and to provide diversity and improved selectivity with respect to protein binding. The macrocyclic ligand intermediates of the prior art are not primarily intended as affinity ligands (i.e. small ligand molecules which bind within a larger 3-dimensional binding site). There is nothing in the prior art to suggest that macrocyclic ring precursors could be used as affinity ligands in their own right, as the intention was to form larger 3-dimensional pockets which would form affinity binding sites for the capture of small molecules, i.e. the exact opposite of 3-D ligands.

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless “there was an apparent reason to combine the known elements in the fashion claimed” by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____ (2007). Furthermore, an applicant's invention is not “proved obvious merely by demonstrating that each of its elements was, independently, known in the (purported) prior art.” *Id.*

A finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, neither of the cited references contain a suggestion that cysteamine, when administered alone or in combination with another agent at a time that is not predetermined through experimentation, can be useful in affecting the level of a biological factor associated with diabetes. It is only the applicants' disclosure that provides such a teaching, and applicant's disclosure

cannot be used to reconstruct the prior art for a rejection under §103. This was specifically recognized by the CCPA in *In re Spinnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Sprock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

Furthermore, as expressed by the CAFC, to support a §103 rejection, “[b]oth the suggestion and the expectation of success must be founded in the prior art...” *In re Dow Chemical Co.* 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). One finds neither the suggestion nor the expectation of success in the cited references, either separately or combined. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103.

In view of the foregoing remarks and the amendment above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



David R. Saliwanchik
Patent Attorney
Registration No. 31,794
Phone: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

DRS/la